**APPLICATION FOR RESEARCHER ACCESS TO CONFIDENTIAL BIRTH DEFECTS MONITORING PROGRAM DATA**
**(M.G.L. c.111, §§ 24A, 24B, 67E, 202, and 105 CMR 305.000)**

## Massachusetts Department of Public Health
## Research and Data Access Review Committee

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### Background

The Birth Defects Monitoring Program ("BDMP") is a critical component of public health strategies to reduce the occurrence and impact of birth defects. The US Centers for Disease Control and Prevention estimate that three to five percent of births have major structural birth defects based on ascertainment by an active surveillance system. Through surveillance, the Massachusetts Department of Public Health is able to detect the prevalence of birth defects in our state, to investigate potential etiologic agents, to plan appropriate interventions, and to ensure services and appropriate care for children with special health care needs.

### Legal Protections Provided by §24A Approval

Massachusetts General Laws Chapter 111, Section 24A, authorizes the Commissioner of the Massachusetts Department of Public Health (MDPH) to approve "...scientific studies and research which have for their purpose the reduction of morbidity and mortality within the Commonwealth." Approval of a research study under §24A provides several important legal protections. It requires that any information collected as part of the study shall be considered confidential and shall only be used for purposes related to conducting the proposed study. All such information procured in connection with a §24A approved study shall not be admissible as evidence in any legal proceeding.[1] Approval of a study pursuant to §24A also provides statutory protection from liability for damages or other relief to any person or institution that provides data or other information to a §24A approved researcher.

In short, authorization of a study under M.G.L. c. 111, §24A, protects the confidentiality of information collected for the study, offers persons and institutions reasonable legal assurances that information which is obtained for an authorized study will not be admissible in any legal proceeding, and provides that persons and institutions providing information for an approved study will be immune from liability for the release of the information.

### Obligations of Researchers Under §24A

Researchers whose studies are approved under §24A have certain obligations. Researchers may use the information obtained for a §24A approved study only for the purposes of medical or scientific research as described by the researcher in the §24A application. Only the principal investigator and his/her authorized collaborators may have access to data or information collected for purposes of conducting the study and may not share such information with any other person or entity unless authorized in writing by MDPH. Approval of a study

[1] §24A approval may not protect the information from subpoena by a criminal defendant and may not protect persons or institutions that provide information when those persons or institutions are located outside of Massachusetts. In some cases the Department collects birth defect monitoring information on births to Massachusetts residents who deliver at birthing hospitals in states that abut Massachusetts and/or newborns who are transferred to hospitals in states that abut Massachusetts.

pursuant to §24A is subject to additional confidentiality conditions imposed by MDPH as specified in the §24A approval letter.

**Review Process for Release of Confidential BDMP Data to Researchers**

The review process occurs under the Massachusetts Department of Public Health's (MDPH) jurisdiction as specified in Massachusetts General laws Chapter 111, Section 24A, Section 24B and 105 CMR 305.000 (for births), Section 67E (for birth defects), and Section 202 (for fetal deaths).

Access to any confidential BDMP records or data must be approved and authorized by the Commissioner of MDPH through the same detailed review process that the Commissioner uses for all medical and scientific studies pursuant to M.G.L. c. 111, §24A. The review process is designed to ensure that confidential birth defect monitoring data collected by MDPH under the authority of G.L. c. 111 s.67E will be accessed only by responsible and qualified researchers who undertake medical and scientific studies for the purpose of the reduction of morbidity and mortality in the commonwealth and who will adhere to the Department's strict requirements for maintaining the confidentiality of the data subjects. Researchers who seek individual record data or aggregate data without cell size suppression must submit a completed application to the Department. Researchers may not obtain access to any more information than is absolutely necessary to complete the proposed study. Please note that some records (such as birth records that have been amended or records of children who are adopted) are further restricted by Massachusetts General Laws and will not be available. Further note that the Department does not maintain records of birth and death that occurred out of state to Massachusetts residents and researchers seeking access to such data will need to apply to the state where the birth or death occurred.

Applicants must submit completed applications to the MDPH Research and Data Access Review (RaDAR) Committee, which includes senior researchers and an attorney from the MDPH Office of the General Counsel. One primary reviewer is assigned to each application to provide a preliminary review and to correspond with the applicant if the information provided is unclear or incomplete. After preliminary review, the application is submitted for review by the RaDAR Committee, where such issues as purpose of the request, potential for reducing the morbidity and mortality within Massachusetts, research design, appropriateness of requested data to answering proposed research questions, provisions for maintaining confidentiality, and the applicant's qualifications will be considered.

The commissioner cannot release any birth defect monitoring data collected under G.L. c.111 s. 67E to a researcher until after the study has received approval from a duly constituted institutional review board. In addition to the RaDAR review and reviews by IRBs based in institutions not affiliated with MDPH, the application may be forwarded to the MDPH Human Subjects Review Committee for its review.

Once an application has been approved by the commissioner of MDPH, the applicant will be asked to co-sign a series of stipulations prior to receiving the requested confidential data. Stipulations include confidentiality provisions, use of the data only for specifically agreed upon purposes, review by MDPH prior to publication or issuance of reports to ensure stipulations have been followed, return of or destruction of the data set following completion of the study and personal and institutional penalties for any noncompliance with stipulations.

MDPH staff, including the Director of the Birth Defects Monitoring Program and members of the RaDAR Committee are available to answer any questions you may have while

preparing the application. Please contact Alice Mroszczyk, Research Review Coordinator, at (617) 624-5616 if you would like assistance.

## Renewal of Authorization

MDPH requires yearly renewal of authorizations pursuant to M.G.L. c. 111, §§24A, 24B, 67E, and 202; reapplication is required after five years. Letters requesting renewal must specify any planned changes in the study, changes of personnel who will have access to the data, and must be accompanied by any reports that have resulted from the study.

## Data Fees

Data used as a result of approved applications are subject to set charges for computer time, programming time, materials, and any other costs incurred by MDPH in producing the requested data. A fee schedule is attached for your information.

# APPLICATION CHECKLIST

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

*Please indicate application materials included:*

| | ✓ or n/a |
|---|---|
| Patient and physician contact protocols | |
| Physician contact letter | |
| Patient contact letter | |
| Contact protocol | |
| Contact script(s) | |
| Informed consent(s) | |
| Subjects | |
| Controls | |
| Institutional agreement for data linkage | |
| Institutional Review Board application | |
| Institutional Review Board comments | |
| Institutional Review Board approval *(If not available, please indicate expected date of decision)* | |
| Response to Attachment B | |
| Variables requested with justification for each | |
| Resumes | |
| Other | |

**Application for Researcher Access to Confidential Birth Defects Monitoring Program Data**
**(M.G.L. c.111, §§ 24A, 24B, 67E, 202, and 105 CMR 305.000)**

## Massachusetts Department of Public Health
## Research and Data Access Review Committee

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**Date of Application:** _____ **Date of Revision:** _____

**PROJECT TITLE:** _____

_____

**PRINCIPAL INVESTIGATOR: (Attach resume)**

**Name and Title:** _____
**Address:** _____

_____

_____

**E-Mail:** _____
**Telephone:** **Extension:** **Fax:**

**Affiliation and source of funding, if different:**
**(organization/institution name and address)**

_____

_____

_____

**PRIMARY CONTACT (If different) Attach resume**

**Name and Title:** _____
**Address:** _____

_____

_____

**E-Mail:** _____
**Telephone:** **Extension:** **Fax:**

**INTENDED START DATE:** **INTENDED COMPLETION DATE:**

_____

**Please submit electronically to:**
**alice.mroszczyk@state.ma.us**
**or you may return *16 copies* of completed application materials to:**

**Alice Mroszczyk**
**Research and Data Access Review CoordinatorMDPH**
**Center for Health Information, Statistics, Research and Evaluation**
**2 Boylston Street, 6th Floor**
**Boston, MA 02116-4737**
**(617) 988-3356**
**Thank you for your cooperation.**

1. List the principal purposes of your project. What are the goals and research questions or hypotheses to be addressed? (Attach additional sheets when necessary.)

2. Explain the public health importance of your project, specifying how it will contribute to the reduction of morbidity and mortality in Massachusetts. Please employ quantitative indicators of public health importance where possible, such as: numbers of deaths or incident cases; age-adjusted, age-specific, or crude rates; years of potential life lost; and so forth.

3. Describe your project. Please provide a detailed plan including specific research questions or hypotheses to be tested and study design. Include a description of study groups (cases, controls, as appropriate), data collection methods, and analytic plan. (Attach additional sheets when necessary.)

Please mark one or more appropriate responses for each question:

4. Will contact with individual subjects in the record and/or their families occur in your project? If yes, please include materials relevant to the currently proposed study.

☐ No contact with subjects and/or families is intended.
☐ Contact with subject in record is intended. *Attach contact protocols, contact letters, and/or scripts.*
☐ Contact with family of subject in record is intended. *Attach contact protocols, contact letters, and/or scripts.*

Explain contact procedure:

If contact with subject or family is intended, do you require records of non-marital births? If yes, why? (These records are restricted by M.G.L. c. 46, §2A.)

5. Will research subjects be asked for their informed consent to participate in your project or for the release and/or use of data pertaining to them?

☐ Yes ☐ No

If yes, *please attach a copy of informed consent form*.

If no, please explain why.

6. Has this project/study been reviewed by an Institutional Review Board or Human Investigations Committee?

☐ Yes ☐ No

If yes, please indicate the name of the committee(s), institution(s), the decision(s) reached, and the date of the review. *Please attach a copy of the application and review.*

If no, please indicate why Institutional Review Board or Human Investigations Committee review has not been sought.

***Please note: in addition to a sponsoring institution's IRB review, this application may be forwarded to the MDPH Human Subjects Review Committee for its review.***

7. If your research study involves the collection, testing and/or storage of human blood, urine, or tissue samples, the Department will require full responses to each of the questions set forth in "Research Involving Human Blood, Urine, or Tissue Collection for Analytical Testing and/or Storage" (See Attachment B). A copy of your responses to the questions in Attachment A will be provided to the MDPH Human Subjects Review Committee.

8. List all data sources and/or data sets that will be used in your project.

9. Will follow-up occur with any data sources?

☐ Yes ☐ No

If yes:

☐ Subjects' medical records will be consulted.

☐ Subjects' physician or other health care provider will be contacted.

☐ Other follow-up source:

_____.

Explain follow-up procedure:

10. Will any linkage of individual records occur across data sets?

☐ No linkage with other data sets is intended.
☐ Linkage only of aggregate data with the following data sets is intended.
☐ Linkage of individual records with the following data sets is intended.

If linkage is planned, please describe in detail:

1. Indicate what data sets will be involved.
2. Describe the purpose for each linkage.
3. List the specific variables and how you are planning to use them for linkage from each data set.
4. Provide a detailed description of the proposed algorithm to be used for linkage. (Note: we recognize that matching is an iterative process that might require changes in the initial algorithm to maximize linkage.)
5. Provide past results of use of this algorithm or experience with similar linkage studies, if any.
6. Please include a flow chart that explains the proposed linkage process. The flow chart(s) should illustrate what files will be linked, what (if any) new data sets will be created, when identifiers will be stripped, etc.
7. Attach a letter of agreement from institution(s) and/or programs whose data set(s) will be linked.

11. Please indicate what years (year of diagnosis) of birth defects monitoring data you wish to access.

12. Please indicate geographical region or location for requested records. Please also specify whether you require records of births to Massachusetts residents or records of all births occurring in Massachusetts.

- ☐ Entire state
- ☐ County
- ☐ CHNA (Community Health Network Area)
- ☐ City or town
- ☐ Hospital
- ☐ Other - specify:_____

Indicate specific county(ies), CHNA(s), city(ies) or town(s), or hospital(s), if not all:

13. Indicate the format in which you would like to receive your data:

- ☐ CD-Rom
- ☐ Zip Disk (provided by requestor)
- ☐ Diskette
- ☐ Computer printout
- ☐ Photocopies of vital records
- ☐ Other, specify_____

14. Please indicate what birth defects are being investigated. Please specify birth defect type(s), including ICD-9 codes that are required.

15. Using the item check list (Attachment A), indicate the items you are requesting and specify which values are required (for example, item: mother's residence, value: Boston only, etc.)

    If you wish to specify the appearance of data tables or listings, please do so here.

16. Provide a short justification for each variable identified in the previous question. Include how the variable will be used in the analysis. Indicate how each variable will be used to address specific research questions or hypotheses described in your analytic plan and what groups of variables will be used in different parts of your analyses. (For example: "Differences in the risk of oral clefts among offspring of women of different races and Hispanic ethnicity will be investigated using logistic regression. Therefore, the variables maternal race (#17) and Hispanic ethnicity (#18) are needed along with cases diagnosed with isolated cleft lip and or palate (ICD codes 749.0, 749.1 and 749.2). The literature indicates that the risk for oral clefts varies by infant sex (#8), maternal age (#15) and maternal smoking (#82 on birth certificate list); thus, those variables are requested. Maternal age in five-year age groups is satisfactory.") *(Attach additional pages.)*

17. Describe the security and storage protection mechanisms to be used in your project. How will individual-record data obtained through this application be stored and maintained? Specifically describe the mechanisms for insuring that data will not be re-released or copied and for limiting access to individuals named in this application.

18. Name those individuals who will require access to the individual-record data or who will see aggregate data without cell size suppression. ***All individuals named in this application as having access to these data will be required to sign written confidentiality agreements****.*

| Name | | Position | | Institution | | Telephone |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

19. Will the results of your project be published?

    ☐ Results will not be published
    ☐ Results will be published

    (Indicate publisher/prospective publisher)_____

***Review by Department of Public Health will be required prior to submission for publication.***

ATTACHMENT A

# Massachusetts Birth Defects Monitoring Program Data
# Variable Checklist

***Please check items required for research and attach a detailed justification for each.***

| ✔ | | **Item** *Availability of all variables may vary by case.* | **Values Requested** *Please specify value groupings (e.g. mother's age groups LT20,20-24, etc)* ***or*** *indicate if all individual values for the variable are required* ***or*** *if a subset is to be provided based on selected values or codes (e.g., Boston only for residence city or Hispanic only for ancestry).* |
|---|---|---|---|
| | 1. | Case ID | |
| | 2. | Birth facility code | |
| | 3. | Birth facility name | |
| | 4. | Birth facility medical record # | |
| | 5. | Other facility code(s) | |
| | 6. | Other facility name(s) | |
| | 7. | Other facility medical record #(s) | |
| | 8. | Sex (M/F/NS) | |
| | | Diagnosis Information | |
| | 9. | BPA/ICD-9 Diagnostic Code(s) | |
| | 10. | Verbatim Diagnosis | |
| | 11. | Laterality of Defect(s) | |
| | | Infant's DOB | |
| | 12. | Year | |
| | 13. | Month | |
| | 14. | Day | |
| | 15. | Mother's age at delivery | |
| | 16. | Father's age at delivery | |
| | 17. | Mother's race | |
| | 18. | Mother's Hispanic ethnicity (Y/N) | |
| | 19. | Livebirth or fetal death | |
| | 20. | Infant death (Y/N) | |
| | 21. | Date of death (infant / fetal death cases only) | |
| | 22. | Place of death (infant / fetal death cases only) | |
| | 23. | Facility of death code (infant / fetal death cases only) | |
| | 24. | Autopsy performed (Y/N/NS/partial) (infant / fetal death cases only) | |
| | 25. | Autopsy date (autopsy performed only) | |
| | 26. | Autopsy location (autopsy performed only) | |
| | 27. | Infant name | |
| | 28. | Mother's name | |
| | 29. | Mother's maiden name | |
| | | Mother's residence at the time of delivery or last known residence | |
| | 30. | Address | |
| | 31. | city name | |
| | 32. | state name | |
| | 33. | zip code | |
| | 34. | Mother's phone # | |
| | 35. | Father's name | |
| | | Father's residence at the time of delivery or last known residence | |
| | 36. | Address | |
| | 37. | city name | |
| | 38. | state name | |
| | 39. | zip code | |
| | 40. | Primary care physician | |
| | | Primary care physician's address | |
| | 41. | Address | |
| | 42. | city name | |
| | 43. | state name | |
| | 44. | zip code | |
| | 45. | Primary care physician's phone # | |
| | 46. | Other MDs/Consults | |

ATTACHMENT A

# Massachusetts Certificate of Live Birth
# Variable Checklist

***Please check items required for research and include values required.***

| ✔ | | Item | Values Requested |
|---|---|---|---|
| | 1. | Certificate number | |
| | 2. | Facility number* | |
| | 3. | Facility name/address** | |
| | 4. | Birth city name/code* | |
| | 5. | Birth county name/code*, ** | |
| | 6. | Birth state name/code** | |
| | 7. | Sex | |
| | 8. | Plurality | |
| | 9. | Birth order | |
| | 10. | Time of birth** | |
| | | Child's birth date | |
| | 11. | Year | |
| | 12. | Month | |
| | 13. | Day | |
| | | Mother's birth date** | |
| | 14. | Year | |
| | 15. | Month | |
| | 16. | Day | |
| | 17. | Mother's age* | |
| | | Mother's birthplace | |
| | 18. | city name/code** | |
| | 19. | state name/code | |
| | | Mother's residence | |
| | 20. | city name/code* | |
| | 21. | county name/code* | |
| | 22. | state name/code | |
| | 23. | zip - 5 digit or 9 digit*, ** | |
| | 24. | census tract*, ** (Boston 80-86) | |
| | 25. | 2 digit neighborhood | |
| | 26. | 4 digit tract code | |
| | 27. | Marital status | |
| | | Father's birthplace | |
| | 28. | city name/code** | |
| | 29. | state name/code | |
| | | Father's birth date** | |
| | 30. | Year | |
| | 31. | Month | |
| | 32. | Day | |
| | 33. | Father's age (begin 1972)* | |
| | 34. | Informant relationship** | |
| | | Certifier information | |
| | 35. | at birth, postnat or cert only** | |
| | 36. | prenatal provider?*** | |
| | 37. | Title | |
| | 38. | in group practice?*** | |
| | 39. | group include CNM's?*** | |
| | 40. | Mother's occupation** | |
| | 41. | Mother's industry** | |
| | 42. | Mother's occup/ind code** | |
| | 43. | Mother's race | |
| | 44. | Mother's ancestry** | |
| | 45. | Mother's language preference*** | |
| | | Mother's education | |
| | 46. | elementary/secondary | |
| | 47. | type diploma*** | |
| | 48. | number years college | |
| | 49. | type degree*** | |

ATTACHMENT A

| ✔ | | Item | Values Requested |
|---|---|---|---|
| | 50. | Father's occupation** | |
| | 51. | Father's industry** | |
| | 52. | Father's occup/ind code** | |
| | 53. | Father's race | |
| | 54. | Father's ancestry** | |
| | 55. | Father's language preference*** | |
| | | Father's education | |
| | 56. | elementary/secondary | |
| | 57. | type diploma*** | |
| | 58. | number years college | |
| | 59. | type degree*** | |
| | 60. | Live births now living | |
| | 61. | Live births now deceased | |
| | 62. | Date last live birth | |
| | 63. | Number terminations | |
| | 64. | Date last termination | |
| | 65. | Parity *(1975 on)* | |
| | 66. | Gravidity *(1975 on)* | |
| | 67. | Date last menses | |
| | 68. | Gestational age based on last mens | |
| | 69. | Gestational age clinical estimate** | |
| | 70. | Date first prenatal visit*** | |
| | 71. | Month prenatal care began | |
| | 72. | Number prenatal care visits | |
| | 73. | Type of prenatal practitioner** | |
| | 74. | Site of prenatal care code/text** | |
| | 75. | Type prenatal health plan cod/txt*** | |
| | 76. | Name prenatal health insurer*** | |
| | 77. | Prenatal care paid by govt*** | |
| | 78. | Type government?*** | |
| | 79. | Prenatal care source of payment<br>*Generated from #75-79 to conform to prior format* | |
| | 80. | Prenatal adequacy of care index | |
| | 81. | Num cigarettes daily pre-preg*** | |
| | 82. | Num cigarettes daily dur preg** | |
| | 83. | Mother's total weight gain/loss** | |
| | 84. | Prenatal tests and procedures**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 85. | Risk factors for this pregnancy**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 86. | Complications of labor and delivery**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 87. | Labor and delivery procedures**<br>*Request Attachment A1 - Restricted Variable List* | |
| | | Method of delivery | |
| | 88. | vaginal | |
| | 89. | vbac | |
| | 90. | forceps | |
| | 91. | vacuum | |
| | 92. | primary csection+ | |
| | 93. | repeat csection+ | |
| | 94. | Type deliv health plan code/text *** | |
| | 95. | Name deliv health insurer*** | |
| | 96. | Delivery paid by government?*** | |
| | 97. | Type government?*** | |
| | 98. | Delivery source of payment**<br>*Generated from #95-98 to conform to prior format* | |

ATTACHMENT A

| ✔ | | Item | Values Requested |
|---|---|---|---|
| | 99. | Birthweight in grams | |
| | 100. | Apgar score - 1 minute (1978 on) | |
| | 101. | Apgar score - 5 minutes (1978 on) | |
| | 102. | Apgar score - 10 minutes*** | |
| | 103. | Congenital anomalies**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 104. | Abnormal cond of newborn**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 105. | Neonatal procedures**<br>*Request Attachment A1 - Restricted Variable List* | |
| | 106. | Is mother breastfeeding?** | |
| | 107. | Mother transf in prior to delivery** | |
| | 108. | Infant transferred and facility** | |
| | 109. | Discharge date and time*** | |
| | 110. | Discharged home with mother?*** | |
| | 111. | Baby alive? | |
| | 112. | Child's name | |
| | 113. | Mother's name** | |
| | 114. | Mother's birth surname | |
| | 115. | Mother's residence address** | |
| | 116. | Mother's mailing address*** | |
| | 117. | Father's name** | |
| | 118. | Informant name***/address** | |
| | 119. | Custodian name/address** | |
| | 120. | Certifier name, lic# /address*** | |
| | 121. | Prenatal practitioner name/add*** | |
| | | Pediatric provider*** | |
| | 122. | has a provider been named: yes/no | |
| | 123. | provider name/address | |
| | 124. | Date of death** | |
| | 125. | Death certificate number | |
| ***ADDITIONAL INFORMATION FOR LINKED BIRTH/INFANT DEATH FILE (FROM DEATH CERTIFICATE)*** | | | |
| | 127. | Facility | |
| | 128. | Date of death | |
| | 129. | Age at death | |
| | 130. | Cause of death | |
| | 131. | Manner of death | |
| | 132. | Referral to medical examiner | |
| | 133. | Assign Unique ID for linkage to births? (if certificate # disallowed) | |

***Please note the following:***

** Please specify value groupings (e.g. mother's age groups LT20,20-24, etc)* ***or*** *indicate if all individual values for the variable are required* ***or*** *if a subset is to be provided based on selected values or codes (e.g., Boston only for residence city or Hispanic only for ancestry).*

*** Indicates items available only after 1986*

**** Indicates items available only after 1995*

*+ C-section data not available prior to 1982*

*Variations in available codes may be found among data years.*

ATTACHMENT B

**RESEARCH INVOLVING HUMAN BLOOD, URINE, OR TISSUE COLLECTION FOR ANALYTICAL TESTING AND/OR STORAGE**

1. Describe the protocols and instructions to be given to the study subjects for providing biomarker samples. Will they be easily understood by study subjects? Do they appropriately describe steps to be taken to safely obtain a sample and describe any risks involved?

2. Will all personal identifiers be removed from the samples? If so, will a key or code be kept which could permit the sample or test result to be "tracked back" to the study subject?

3. Describe the security procedures for storage of biomarker samples, including place of storage, security of storage, length of time of storage, and destruction plans.

4. Provide a precise description of the specific intended uses of biomarker samples. What kind of tests will be performed? Are there clear limits on the type(s) of tests that may be performed? How do the intended uses of the biomarker samples and any tests that may be performed relate to study hypotheses?

5. Provide assurance that biomarker samples, either identified or unidentified, will not be reused for any other study or tested in any manner not previously consented to by the study subject without further explicit written informed consent from the study subject.

6. Provide assurance that biomarker samples, either identified or unidentified, will not be sold or used for commercial purposes, without explicit informed consent from the study subject.

7. Describe the extent to which there may be linkage of biomarker sample and test results with other information, including survey responses, medical records, and MDPH confidential records. For example, will test results be recorded in the study subject's medical record? Does the consent form fully inform the study subject about the nature and extent of such linkage?

8. Describe whether and how test results will be communicated back to the study subjects or their physicians. If test results will be shared with the study subject or physician, will the study subject be given information about the reliability and accuracy of genetic tests, the information the tests will provide and the reliability of that information? Will the study subject be made aware of ethical and other issues and risks that may arise once the study subject obtains such information? Will the study subject be informed about the availability of genetic counseling?

9. Does the informed consent form contain full disclosure regarding:
   (a) purpose of study,
   (b) #2-8 above,
   (c) rights to request destruction of a subject's biomarker sample at any point during or after study;
   (d) name of principal investigator and telephone number for answering questions regarding study participation?

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

CHRISTINE C. FERGUSON
COMMISSIONER

# The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
250 Washington Street
Boston, Massachusetts 02108-4619

## FEE SCHEDULE

effective July 2003

**Requests for data maintained by Bureau of Health Statistics, Research and Evaluation (per M.G.L. c.7, 3B, M.G.L. c.66, 10 and 950 CMR 32.00, M.G.L. c.111, §24A, B, 111B, and 202; M.G.L. c.262, 44A)**

**Telephone: (617) 740-2670**

| Unit | Description | Rate |
|---|---|---|
| | **PERSONNEL** | |
| hour | Programmer | 27.00 |
| hour | Epidemiologist | 29.00 |
| hour | Clerical | 16.00 |
| hour | Other | |
| job | Computer CPU Charges | |
| | **OUTPUT/MEDIUM** | |
| page | Laser | .50 |
| page | Photocopy | .20 |
| each | Diskette | 1.25 |
| each | Zip Disk | 12.00 |
| each | CD | 1.50 |
| | **VITAL RECORDS** | |
| Certified copy | Certificates: Birth/Death etc. | 18.00 (on-site)<br>28.00 (by mail) |
| each | **PUBLICATION**<br>Call for a list of available publications. | Cost |
| each | **POSTAGE**<br>***Please note: confidential data are sent by tracked mail.*** | Cost |
| each | **OTHER CHARGES** | Cost |

**All rates subject to change. Job estimate is an approximation, not a cost quotation. Delivery made upon receipt of payment.**